

Appl. No. 09/508,510
Amdt. Dated October 25, 2004
Reply to Office Action of May 25, 2004

Listing of the Claims

1-2. Canceled

3. (Currently amended) A liquid formulation comprising a glycosylated human interferon- β as an active ingredient, a buffer which buffers in a pH range of 5 to 8, and methionine present in a concentration of 0.1 to 4 mmol/l, with the proviso that the formulation does not contain human serum albumin, and wherein after storage for 3 months at 25°C, stability of an in vitro biological activity of the formulation is at least 80% of an initial biological activity, wherein said biological activity comprises inhibition of a cytopathic effect of a virus.

4-8. Canceled.

9. (Previously presented) The formulation according to Claim 3, wherein the pH is between 6 and 7.2.

10. Canceled.

11. (Currently amended) The formulation according to Claim 3, wherein the formulation, apart from the active ingredient, is free from ~~human or~~ animal polypeptides.

12. (Previously presented) The formulation according to Claim 3, wherein the formula is free from surfactants.

13. (Currently amended) The formulation according to Claim ~~[[1]]~~ 3, wherein after storage of the formulation for 6 months at 25°C, the formulation is chemically stable.

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14. (Currently amended) The formulation according to Claim ~~[[1]]~~ 3, wherein after storage of the formulation for 6 months at 25°C, the formulation is physically stable.

15-17. Canceled.

18. (Previously presented) The formulation according to Claim 3, further comprising an ingredient for adjusting tonicity.

19. (Previously presented) The formulation according to Claim 3, comprising a thickener for increasing viscosity.

20. (Previously presented) The formulation according to Claim 3, further containing at least one physiologically acceptable preservative.

21-26. Canceled.

27. (Previously presented) A pharmaceutical composition comprising a liquid formulation according to Claim 3, and a pharmaceutically acceptable carrier.

28. (Previously presented) The pharmaceutical composition according to Claim 27 in a form suitable for oral, parenteral or ophthalmological administration.

29. (Previously presented) The pharmaceutical composition according to Claim 27, wherein the composition is in the form of a unit containing 1 to 25×10^6 IU of interferon- β .

30-31. (Canceled)

32. (Previously presented) A liquid formulation consisting of human interferon- β , 70 mmol/L sodium citrate, 50 mmol/L sodium phosphate, and 2 mmol/L methionine, having a pH in a range of about 6.2 to about 6.8.

33. (Previously presented) The liquid formulation of claim 32, wherein the formulation has a pH of about 6.5.

34. (New) The liquid formulation of claim 3, wherein the methionine is present in a concentration of 2 mmol/L.

35. (New) A method for increasing the long-term stability, including the in vitro biological activity stability, of a liquid formulation comprising human interferon- β as an active ingredient, said method comprising adding a buffer for buffering in a pH range of 5 to 8, while avoiding the presence of human serum albumin in the formulation, and adding a stabilizing amount of methionine to the formulation, wherein the stabilizing amount of methionine is a concentration of methionine that is 0.1 to 4 mmol/L.

36. (New) The method of claim 35, wherein the stabilizing amount of methionine is a concentration of methionine that is 2 mmol/L.

37. (New) The formulation of claim 32, wherein the human interferon- β has a concentration of about 10×10^6 IU/ml to about 15×10^6 IU/ml.

38. (New) The formulation of claim 37, wherein the human interferon- β has a concentration of about 12×10^6 IU/ml.